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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/018,160

11/01/2001

Ronald Alan Coffee

13401

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24116 7590 10/16/2008
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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/018,160	Applicant(s) COFFEE ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) claims 4-9, 11, 13-16, 34-38, 40-42, 55, 58-60 and 71-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) claims 4-9, 11, 13-16, 34-38, 40-42, 55, 58-60 and 71-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, in the reply filed on 07/15/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 4-9, 11, 13-16, 34-38, 40-42, 55, 58-60 and 71-95 are pending and presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 7-9, 11, 13-16, 34-40, 55, 58-60, 71-76, 78-83 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267) and Roche et al (US 5,215,755) in view of Kovacs et al (US 5,322,698).

Coffee discloses processes and apparatuses for forming material by electrohydrodynamic comminution (See Abstract; and Page 4, Lines 1-4). In one

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aspect, the processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (See Page 2, Line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biologically active components for topical application such as analgesics, antiseptics, antibiotics, antifungals, antibacterials, antiparasitics, debridement agents, and biological material, such as fibrin or collagen may also be formed using the processes and apparatuses (See Page 5, lines 29-35 and 6, Lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles (See Page 5, Lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form of a liquid that is dispensed through an outlet nozzle (See Page 22, Lines 23- 33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (See Page 19, Lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (See Claim 32; and Page 30, Lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (See Page 11, Lines 17-22).

The Roche et al. patent is used here merely as a teaching reference to show that additives such as saccharin and peppermint flavoring are commonly known in the pharmaceutical arts (See Column 8, Lines 34-65+).

As explained above, the Roche et al. patent is relied upon merely as a teaching reference. It is the position of the examiner that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. Though the prior art is silent with respect to a cutting step in the disclosed method of production, as the prior art has disclosed the manufacture of particles in addition to fibers and mats, it is the view of the examiner that the use of a cutting step is would be within the level of skill of one of ordinary skill in the art.

Coffee and Roche meets claims limitation as stated above but fails to include vinylpyrrolidone/vinylacetate copolymer as biologically acceptable polymer in the process of manufacturing tablets.

Kovacs discloses a process for the preparation of a tablet or dragee composition containing active ingredient. And tablet prepared by direct compression possesses an appropriate hardness and making possible the rapid absorption and resulting in a high bioavailability of the active ingredient (see abstract and col. 2 lines 24-34). And also discloses suitable additives such as binding agents (water-soluble cellulose ethers or polyvinylpyrrolidone, vinylpyrrolidone/vinylacetate copolymer, and pharmaceutically acceptable organic solvents such as ethanol, isopropanol acetone or their mixtures (see col. 3 lines 44-55)).

It would have been obvious to one of ordinary skill in the art to combine the disclosures of Coffee and Roche for the process of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, mats and tablets, as taught by Coffee and Roche and combine it with the tablet composition

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capable of rapid absorption into blood and resulting in a high bioavailability of the active ingredient, as taught by Kovacs, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Coffee teaches a method and/or a device for forming solid, partially solid or gel-like matter such as fibers, fibrils or fiber fragments or segments, droplets or particles by an electrohydrodynamic process.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claims 4-9, 11, 13-16, 34-38, 40-42, 55, 58-60 and 71-95 rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267) and Roche et al (US 5,215,755) in view of Kovacs et al (US 5,322,698) as applied to claims 7-9, 11, 13-16, 34-40, 55, 58-60, 71-76, 78-83 and 85-95 above, and further in view of Hansen et al (US 6,423,346 B1).

Coffee, Roche and Kovacs meets the claim limitations as stated above but fails to include fish gelatin as biologically acceptable liquid carrier.

Hansen discloses a tablet comprising conventional excipients and a particulate composition therein, whereby the particulate composition contains one or more physiologically active substances and fish gelatin. And in addition to fish gelatin, composition comprises, exudates such as cellulose derivates, modified starches,

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synthetic hydrocolloids, such as polyvinyl alcohol, polyvinyl pyrrolidone and mixtures thereof (see abstract and col. 3 lines 42+).

It would be obvious to one of ordinary skill in the art to combine the disclosures of Coffee, Roche, Kovacs and Hansen, into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Coffee, Roche and Kovacs references in order to devise a continuous method of manufacturing dosage forms that utilizes a more sophisticated method of producing a mat that is created from fibers containing an active ingredient. As explained above, the Roche and Kovacs patents are relied upon merely as a teaching reference. Because, Coffee teaches a method and/or a device for forming solid, partially solid or gel-like matter such as fibers, fibrils or fiber fragments or segments, droplets or particles by an electrohydrodynamic process and Hansen teaches using fish gelatin to obtain tablet having plurality advantageous results (high mechanical strength), that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation, and as such as not considered to impart a patentable distinction above the prior art, without a showing of unexpected results. Claims limitations, reciting specific moist tissue surfaces are considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

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